REMARKS

This is in response to the Office Action mailed September 20, 2002 for the above-captioned application. Applicants request a three month extension of time and enclose the appropriate fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

Reconsideration and further examination of the application, as amended, are respectfully requested.

The Examiner indicated that claims 15-16 were allowable, if the rejection under 35 U.S.C. § 112 is overcome. Applicants advise the Examiner that the hybridoma's, which were deposited with the European Collection of Cell Cultures and assigned the indicated numbers are publicly available and have been publicly available since the publication of the European Application. The Examiner also requested clarification of the intended scope of the claims. The claims are intended to encompass that monoclonal antibody that is expressed by the hybridoma, but not to be a product by process claim. In other words, sequencing the antibody produced by the hybridoma or otherwise making it by other means would still fall within the scope of the claims. The Examiner's inquiry as to how many "different monoclonal antibodies" are expressed by each deposit is inconsistent with them being monoclonal. In view of the foregoing, Applicants submit that claims 15 and 16 are in form for allowance.

Claims 1-14 have been cancelled and replaced with new claims 18-35. Applicants submit that these claims address the rejections under 35 U.S.C. § 112, second paragraph. Accordingly, this rejection will not be addressed further.

The Examiner rejected claim 1 as anticipated by Hashimoto et al. This rejection is mooted by the amendment to the claims, since Hashimoto does not deal with a gonadotropin.

The Examiner rejected claims 1-4 and 13-14 as anticipated by Rafferty. Rafferty reports results of a study to assess isoforms of FSH using different binding entities. Rafferty does not disclose an assay which is effective to determine the menopausal condition of an individual female, nor does Rafferty provide any indication that determination of FSH isoforms would provide information sufficient to make such a determination. Thus, Rafferty does not anticipate any of the amended claims.

The Examiner rejected claims 1-4, 13 and 14 as anticipated by US Patent No. 5,262,518 of Chappel. The Chappel patent relates to a kit for inducing ovulation. It has nothing directly to do with detection of menopausal state. All Chappel states is the well known fact that FSH derived from post-menopausal women contains more heavily sialylated isoforms. This is a statement about an average pooled-population derived form many women, however. Nothing about Chappel teaches the determination of FSH isoforms as a means for assessing the menopausal status of an individual human female, or suggests that it would even be possible. Thus, Chappel does not anticipate the present claims.

The Examiner rejected claims 1-3 and 13 as anticipated by Evans et al. Evans deals with detection of a form of activin, a glycoprotein dimer that has the ability to stimulate FSH synthesis and secretion. FSH is produced by the pituitary gland. Thus, activin is not a gonadotropin since it does not act on the gonads (ovaries or testes). Accordingly, Evans does not anticipate the amended claims. Furthermore, nothing in Evans suggests that activin could be used to determine the menopausal state of an individual human female. Indeed, on Page 221, col 2, the Abstract states that lower concentrations of activin A were detected in postmenopausal serum, normal cycle serum and serum from gonadotropin treated women.

The Examiner stated that claims 10-14 are anticipated by Magginetti. This reference has nothing to do with determination of menopausal condition. Amended apparatus claim 31 requires means for combining the signals for the first and second gonadotropin-responsive signal producing means to provide an indication of the menopausal status of the human female individual. This is plainly absent from Magginetti thus rendering the rejection moot.

Claims 10, 12 and 13 were rejected as anticipated by May et al. (WO 88/08534). This reference has nothing to do with determination of menopausal condition, and does not disclose means for combining the signals for the first and second gonadotropin-responsive signal producing means to provide an indication of the menopausal status of the human female individual. Thus, the amended claims are not anticipated.

Claims 10-11 and 13 were rejected as anticipated by US Patent No. 5,830,680 of Meyerhoff et al. Again, this reference has nothing to do with determination of menopausal condition, and does not disclose means for combining the signals for the first and second

gonadotropin-responsive signal producing means to provide an indication of the menopausal status of the human female individual. Thus, the amended claims are not anticipated.

For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

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